Application No.: 09/747,760 Amendment dated March 4, 2003 Reply to Office Action of November 4, 2002

REMARKS

I. Status of the Claims

Claims 1-21 are pending, with claims 3-21 withdrawn as directed to a non-elected invention. Upon entry of the amendment, claims 1 and 2 are amended without prejudice or disclaimer.

II. Restriction

The Examiner maintains that examining the claims in Group I and II would constitute an undue burden on the Office. The rationale given is that the claims of Group I are drawn to methods in which the effect of a candidate drug on the expression of a single gene is monitored. The claims in Group II, in contrast, are said to involve a determination of the effect on multiple genes. Thus it is concluded that the search of the claims in Group II would require searching additional art that would be unduly burdensome.

In response, it is first noted that the Examiner has mischaracterized the scope of claim 1, the base claim in Group I. Claim 1 encompasses methods in which the effect on expression of a single gene or multiple genes is determined. This is evidenced, in part, by the fact that claims 3-11 which can involve the determination of an effect on multiple genes depend upon claim 1. If claim 1 did not encompass methods that involve the determination of the effect on multiple genes, then claims 3-11 would not properly depend upon claim 1. Claim 1 as amended makes explicit what was previously implicit in the claim, namely that the method encompasses the possibility that the effect on multiple genes is determined.

Second, the process described in MPEP 803.02 is applicable to the question of whether examination of the claims in Group II (i.e., claims 3-11) would impose an undue burden on the Office. According to this section, when, as here, a species from a Markush group has been elected, examination of all the species in the Markush group must be examined, unless art is identified that anticipates or renders obvious the elected species. For the reasons set forth below, current claim 1 is patentable over the cited art. So examination should continue with respect to

Application No.: 09/747,760 Amendment dated March 4, 2003

Reply to Office Action of November 4, 2002

the non-elected species. If art is not identified that renders one of the non-elected species unpatentable, the Examiner will have reviewed all the art pertinent to claims 3-11. In which case, it is requested that the Examiner rejoin the claims in Group II.

III. Objections to Specification and Claims

The specification is objected to for not including a specific reference to the application to which priority is claimed. In response, it is noted that the transmittal letter filed with the application included an instruction to amend the specification to include such a reference. Nonetheless, the current amendment requests insertion of a new "Cross-Reference to Related Application Section" that provides the necessary reference. It is requested that this reference be inserted in lieu of the reference made on the transmittal letter. It is noted that incorporation of the priority application is consistent with the reference statement on the transmittal letter. So this amendment introduces no new matter.

Claim 1 is objected to because it refers to genes by their abbreviated names. This claim has been amended to indicate the full name of the gene where available. These amendments add no new matter.

The specification is also objected to because of the use of certain trademarks. The specification has been amended as requested.

The specification is further objected to for allegedly attempting to incorporate essential material in non-U.S. patent documents. No indication is provided, however, as to which documents are deemed essential and the reason why they are considered essential to the currently claimed invention. Clarification is requested.

IV. Rejection of Claims under 35 U.S.C. 102(b) and 35 U.S.C. 103(a)

A. <u>Currently Claimed Invention</u>

Claim 1 has been amended to clarify that the currently claimed invention is directed to a method for screening drug candidates for effect on expression of one or more of the

Application No.: 09/747,760

Amendment dated March 4, 2003

Reply to Office Action of November 4, 2002

recited expression profile genes in B cells. Support for the claim as amended can be found, for example, in FIGS. 1A and 1B, original claim 4; page 16, lines 3-4; and page 17, lines 11-12.

B. Rejection of Claims under 35 U.S.C. 102(b)

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,580,722 to Foulkes ("Foulkes"). Foulkes discusses methods for identifying chemicals that modulate the expression of certain genes that are associated with cardiovascular disease. It fails, however, to discuss a method such as currently claimed in which a candidate drug is screened to determine its effect on the gene expression of the listed markers in B cells. Foulkes, in fact, includes no discussion of gene expression in B cells at all. Because Foulkes does not teach each element of the presently claimed invention, it is requested that this rejection be withdrawn.

C. Rejection of Claims under 35 U.S.C. 103(a)

Claims 1 and 2 are rejected as allegedly being obvious over PCT Publication WO 97/10365 to Lockhart et al ("Lockhart") in view of U.S. Patent No. 6,110,666 to Grosveld ("Grosveld"). Lockhart is said to discuss general methods for conducting array-based expression analysis, including detecting changes in expression due to exposure of drugs. Grosveld is said to discuss CD72 (the elected species gene) as a marker for "pre-B cells." The combination of these teachings is said to render the current claims obvious.

The currently pending claims, however, are not directed to screening methods that determine the effect of drugs on "pre-B cells." Instead, the methods are conducted with "B cells," which are further along the lymphocyte differentiation pathway. So the teachings of the two cited references, even when combined, fail to teach or suggest each and every element of the currently claimed invention. It is thus submitted that this ground of rejection should also be withdrawn.

Application No.: 09/747,760 Amendment dated March 4, 2003 Reply to Office Action of November 4, 2002

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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